Remarks

Claims 34-40 and 47-49 are pending in the subject application. By this Amendment, Applicants have amended claim 37. Support for the amendments can be found throughout the subject specification and in the claims as originally filed (see, for example, page 48, lines 22-24, of the specification). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 34-40 and 47-49 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants gratefully acknowledge the Examiner's withdrawal of the objections to the specification and the rejection under 35 U.S.C. §102(b) over Pan *et al.*

Claims 37, 40, and 49 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The Office Action indicates that the recitation of the limitation "at least six consecutive amino acids ... spans positions 92 and 98" causes the claim to be vague and indefinite. Applicants respectfully submit that claim 37 is not vague or indefinite. Applicants respectfully submit that the plain reading of the claim indicates that the claimed fragment is at least six consecutive amino acids of SEQ ID NO: 58 and that the fragment contains at least six of the amino acids located at positions 92 through 98 of SEQ ID NO: 58. However, in the interest of expediting prosecution in this matter, Applicants have amended claim 37 in a fashion that renders this issue moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 37, 40, and 49 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention; however, in the interest of expediting prosecution in this matter, Applicants have amended claim 37 to delete the limitation of "fragment spans positions 92 and 98 of SEQ ID NO: 58" thereby rendering this rejection moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 34-49 are rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, on the ground that the claimed invention is not supported by a well-established utility. The Office Action

argues that the utilities indicated within the specification are non-specific or particular to the claimed sequence. For example, the Office Action argues that the use of the claimed sequence as a substrate for various proteases, in animal models, for the diagnosis of diseases or disorders associated with abnormalities of the metabolism of collage or the monitoring of collagen degradation are non-specific uses that are applicable to a large family of structurally related collagen related proteins and which are not specific to the polypeptide being claimed. Applicants, again, respectfully traverse.

The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. *See In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility."). It is respectfully submitted that the Office Actions issued in this matter have failed to provide any evidence showing that the asserted utility would be doubted by those of ordinary skill in the art.

In the initial Office Action, the Patent Office argued that the asserted utilities of the claimed polypeptide was not credible, specific, or substantial on the grounds that the paper first reporting the isolation of the human alpha 1 type XVI collagen (also known as COL16A1) authored by Pan *et al.* in 1992 states that "structural similarities between the α1 type XVI collagen and the FACIT group raise the intriguing possibility that the α1(XVI) collagen may serve similar functions". This position has been maintained in the subsequent Office Action.

Applicants respectfully submit that the Office Actions fail to take into account further information developed with regards to α1 type XVI collagen after the publication of Pan *et al.* For example, a number of splice variants of the human alpha 1 type XVI collagen are known (see attached EMBL-EBI Altsplice printout indicating eleven (11) known splice variants). Additionally, review texts documenting the state of the art for what the authors termed "unconventional collagens" (including human alpha 1 type XVI collagen) have been written (see *Unconventional Collagens Types VI, VII, VIII, IX, X, XIV, XVI and XIX*, S. Ricard-Blum *et al.*, Oxford Press, 2000, attached hereto), and, as indicated in the attached ENTREZ PROTEIN and ENTREZ GENE printouts, members of this collagen family are found in association with fibril-forming collagens such as type I and II and serve to maintain the integrity of the extracellular matrix. Finally, high levels of type XVI

collagen have been found in fibroblasts and keratinocytes, and in smooth muscle and amnion. Thus, it is respectfully submitted that the Patent Office has failed to show that one skilled in the art would reasonably doubt the utilities asserted with respect to the claimed polypeptide, particularly in view of the knowledge regarding such polypeptides that was gathered subsequent to the publication of Pan *et al.*

As set forth in the specification, the instantly claimed invention has utility for: the diagnosis of diseases or disorders associated with abnormalities of the metabolism of collagen; use in assays (*in vitro*) as a substrate of proteases; the treatment of diseases and conditions associated with collagen matrix destruction, including for wound treatment; for preparing cosmetic compositions such as skin creams with anti-wrinkle activity; or use as an injectable biomaterial. Applicants respectfully submit that the fact that the claimed polypeptide has certain uses that overlap with other structurally related proteins (collagens) is not controlling as to whether the claimed polypeptide has a utility that is specific, credible, substantial or well-established. For example, the subject specification indicates that the claimed polypeptide can be used as an injectable biomaterial or in cosmetic compositions. As the Patent Office may be aware, injectable collagen is used in the fields of plastic surgery for a variety of purposes, including for lip augmentation and to rectify facial defects, frown lines and acne scars (see paragraph 983 of the published application). Thus, it is respectfully submitted that one skilled in the art would recognize that the instantly claimed invention would have a specific, credible, substantial and well-established utility for use in the field of plastic surgery as an injectable composition. Further, it is respectfully submitted that one skilled in the pertinent arts would be able to use the subject invention in view of the teachings of the application and/or the skill/knowledge of the artisan of the relevant field of endeavor. Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

Claims 37, 40, and 49 are rejected under 35 U.S.C. § 102(b) as anticipated by Olsen *et al.* (1999). The Office Action states that the Olsen *et al.* reference discloses a collagen polypeptide fragment comprising at least six consecutive amino acids which spans positions 92 and 98 of SEQ ID NO: 58. Applicants respectfully submit that the cited reference does not anticipate the presently claimed invention. However, by this Amendment, Applicants have amended claim 37 to delete the limitation of "fragment spans positions 92 and 98 of SEQ ID NO: 58" thereby rendering this

rejection moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

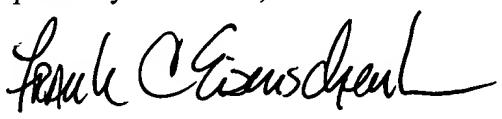
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.
Patent Attorney
Registration No. 45,332
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/sl
Attachments: EMBL-EBI Altsplice printout
Unconventional Collagens Types VI, VII, VIII, IX, X, XIV, XVI and XIX, S. Ricard-Blum *et al.*, Oxford Press, 2000, abstract only
ENTREZ PROTEIN and ENTREZ GENE printouts

ASD **AltSplice Entry Display**

Help

Altsplice-Human : Entry ENSG00000084636

GENE INFORMATION :	
Gene symbols :	COL16A1 , 447AA , FP1572
Protein description :	Collagen alpha 1(XVI) chain precursor. [Source:Uniprot/SWISSPROT;Acc:Q07092]
Gene sequence :	View the gene sequence

CHROMOSOME INFORMATION :	
Chromosome :	1
Contig start-end :	31783941 - 31841742
Strand :	Minus

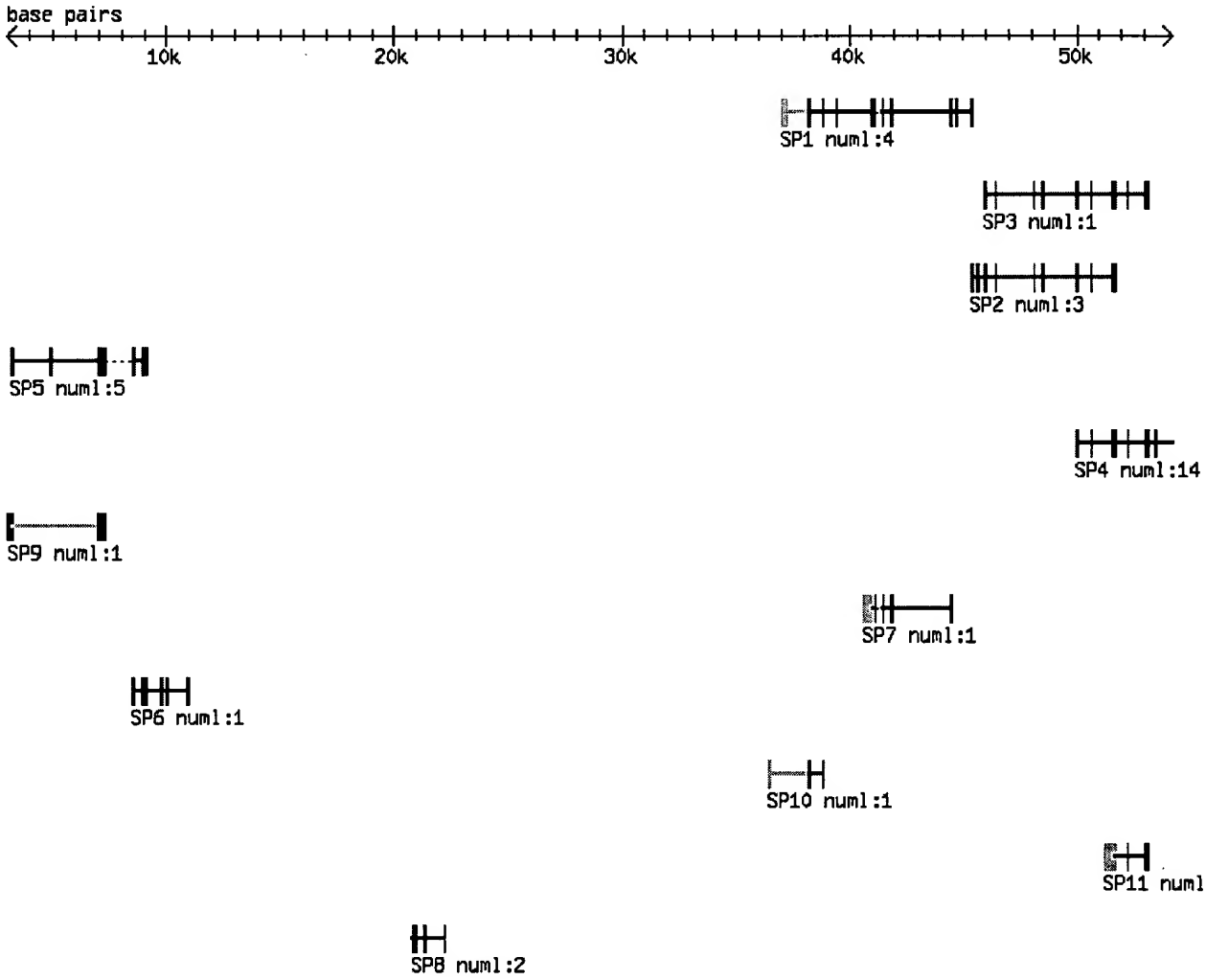
CROSS REFERENCES :	
EnsEMBL gene :	ENSG00000084636
EnsEMBL Transcript/Peptide :	ENST00000271069 (ENSP00000271069.5)
Uniprot/SwissProt :	Q07092
EMBL :	M92642 , S57132
REFSEQ :	NP_001847 , NM_001856
GO :	GO:0007155 , GO:0007565 , GO:0006817 , GO:0005201 , GO:0005737 , GO:0005578 , GO:0005597
PROTEIN ID :	AAA58427 , AAB25797
INTERPRO :	IPR003979 , IPR000694 , IPR002965 , IPR008160

GENE ONTOLOGY :	
MOLECULAR FUNCTION :	structural molecule activity ; extracellular matrix structural constituent : (GO:0005201)
	extracellular region ; extracellular matrix (sensu Metazoa) : (GO:0005578)

CELLULAR COMPONENT :	extracellular region ; extracellular matrix (sensu Metazoa) ; collagen : (GO:0005597) cell ; intracellular ; cytoplasm : (GO:0005737)
BIOLOGICAL PROCESS :	physiological process ; cellular physiological process ; transport : (GO:0006817) physiological process ; organismal physiological process ; reproductive physiological process : (GO:0007565) cellular process ; cell communication ; cell adhesion : (GO:0007155)

EVIDENCES :		
Human-Mouse Conservation :	o Intron/Exon level	ENSMUSG00000040690

Confirmed introns/exons :	Clik on this link displays a page giving reference transcript structure and confirmed introns/exons



CLICK HERE FOR ADDITIONAL FUNCTIONALITIES

Splice Pattern Viewer

Legend : A dashed line between features indicates a gap on the pattern where an intron couldn't be fully confirmed.
numl: number of libraries that confirm this pattern.
SP: indicates the index of the splice pattern. Putting the mouse pointer over a "SP" text ("mouse-over") brings up a pop-up window with expression state information, links to splice pattern table (with the appropriate splice pattern as high-lighted) along with expression state information and pattern sequence.
Putting the mouse pointer over an exon/intron feature brings up a pop-up window with link to sequence page of the feature.

Splice patterns on Ensembl browser

Show Splice Patterns along the contig via Ensembl DAS source

How do I set the DAS server up for the first time ?

Splice Pattern Table

PATTERN SEQUENCE	PEPTIDE SEQUENCE	STRUCTURE	CONFIRMING EST/mRNA's	CLONE LIBRARIES	IDENTIFIED SNP's
1		~37048..37238, 38194..38247, 38831..38884, 39421..39474, 40968..41012, 41114..~41168, ~41431..41466, 41815..41877, 44391..44462, 44662..44715, 45345..~45384	4	4	19
2		~45352..45389, 45591..45635, 45930..45983, 46411..46464, 48085..48135, 48472..48561, 49981..50016, 50605..50649, 51547..~51736	3	3	11
3		~45928..45983, 46411..46464, 48085..48135, 48472..48561, 49981..50016, 50605..50649, 51547..51735, 52191..52257, 53006..~53145	2	1	15
4		~49981..50016, 50605..50649, 51547..51735, 52191..52257, 53006..53182, 53373..53450, 54196..~54237	16	14	12
5	4856.9125 (211 aa)	~3184..3212, 4822..4928, 6934..7008, 7119..~7236, ~8445..8566, 8877..~9143	7	5	11
6		~8465..8566, 8877..9143, 9749..9829, 9961..10086, 10908..~10963	1	1	4
7		~40664..41012, 41114..~41168, ~41431..41466, 41815..41877, 44391..~44462	1	1	4
8		~20768..20805, 20914..20958, 21279..21410, 22193..~22229	3	2	3

9	~2989..3212, 6934..7008, 7119..~7236	1	1	7
10	~36406..36493, 38194..38247, 38831..~38885	1	1	7
11	~51201..51735, 52191..52257, 53006..~53183	2	2	5

o View all the splice pattern sequences

Splice Events :

Cassette Exon Event			
CASSETTE EXON(s)	EVENT TYPE	AEDB ASSOCIATION	CONSERVATION
4822..4928	SCE		

Home

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1: J Cell Sci. 2000 Dec;113 (Pt 23):4141-2.

Unconventional collagens

Knight DP.

Unconventional Collagens Types VI, VII, VIII, IX, X, XIV, XVI and XIX by S. Ricard-Blum, B. Dublet and M. van der Rest Oxford University Press (2000) pp.155. ISBN 0-19-850545-0 35.00 This thoroughly researched monograph in Oxford University Press's 'Protein Profile Series' reviews substantially all the significant literature on this interesting and highly important group of proteins. The authors use the term 'Unconventional Collagens' for the collagens of higher vertebrate connective tissues which do not, of themselves, form classical fibrils with a 68 nm banding pattern. The authors chose to omit type IV collagen as this, they claim, would have almost doubled the size of the volume. The monograph represents a very considerable achievement in three respects. Firstly it comprehensively reviews the literature on the sequence, structure, expression, post-translational modification, genetics, physiological function and pathology of each separate unconventional collagen. The thoroughness of this review is indicated by the fact that the bibliography contains no fewer than 1196 references. Secondly, the monograph identifies the modular domain structure for each collagen, clearly demonstrating that these proteins are block co-polymers mainly derived in evolution from a small number of ancestral genes. Thirdly, it starts to identify the way in which the different modules of these sticky molecules interact with each other and with other connective tissue components. This is an important start if we are to understand their vital role in the self-assembly processes which occur in embryology, tissue repair and the major degenerative and collagen gene diseases The clearly written and well set out text is supported by excellent micrographs of rotary shadowed molecules and molecular aggregates and a wealth of diagrams and tables. The book has, in my view, three minor shortcomings: a short summary chapter on type IV would enable the non-specialist reader to relate this collagen to the other non-conventional collagens. Concise summaries at the ends of each chapter would orient newcomers to the field. More significantly, apart from the brief introduction, the book lacks an overall synthesis which pulls together the findings of the separate chapters. These slight limitations aside, this book is essential reading for those engaged in connective tissue research and will do much to stimulate further activity in this area. It will also be of considerable interest to tissue engineers, pathologists and embryologists.

PMID: 0011069758 [PubMed - as supplied by publisher]

1: NP_001847. Reports alpha 1 type XVI ...[gi:18641352]


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LOCUS       NP_001847               1603 aa            linear   PRI 16-OCT-2005
DEFINITION  alpha 1 type XVI collagen precursor [Homo sapiens].
ACCESSION   NP_001847
VERSION     NP_001847.2  GI:18641352
DBSOURCE    REFSEQ: accession NM_001856.2
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SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
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            Mammalia; Eutheria; Euarchontoglires; Primates; Catarrhini;
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REFERENCE   1  (residues 1 to 1603)
  AUTHORS   Kassner,A., Tiedemann,K., Notbohm,H., Ludwig,T., Morgelin,M.,
            Reinhardt,D.P., Chu,M.L., Bruckner,P. and Grassel,S.
  TITLE     Molecular structure and interaction of recombinant human type XVI
            collagen
  JOURNAL   J. Mol. Biol. 339 (4), 835-853 (2004)
   PUBMED   15165854
  REMARK    GeneRIF: interacts with fibrillin-1 and with fibronectin indicating
            multiple molecular interactions in which this ubiquitously
            expressed and versatile fibril-associated collagens with
            interrupted triple helices-collagen can participate
REFERENCE   2  (residues 1 to 1603)
  AUTHORS   Kassner,A., Hansen,U., Miosge,N., Reinhardt,D.P., Aigner,T.,
            Bruckner-Tuderman,L., Bruckner,P. and Grassel,S.
  TITLE     Discrete integration of collagen XVI into tissue-specific collagen
            fibrils or beaded microfibrils
  JOURNAL   Matrix Biol. 22 (2), 131-143 (2003)
   PUBMED   12782140
  REMARK    GeneRIF: Not in banded collagen fibrils in dermis, but is component
            of specialized fibrillin-1-containing microfibrils. In cartilage
            matrix not in aggregates with fibrillin-1. Resides in thin, weakly
            banded collagen fibrils also containing collagens II and XI.
REFERENCE   3  (residues 1 to 1603)
  AUTHORS   Grassel,S., Timpl,R., Tan,E.M. and Chu,M.L.
  TITLE     Biosynthesis and processing of type XVI collagen in human
            fibroblasts and smooth muscle cells
  JOURNAL   Eur. J. Biochem. 242 (3), 576-584 (1996)
   PUBMED   9022684
REFERENCE   4  (residues 1 to 1603)
  AUTHORS   Sires,U.I., Dublet,B., Aubert-Foucher,E., van der Rest,M. and
            Welgus,H.G.
  TITLE     Degradation of the COL1 domain of type XIV collagen by 92-kDa
            gelatinase
  JOURNAL   J. Biol. Chem. 270 (3), 1062-1067 (1995)
   PUBMED   7836360
REFERENCE   5  (residues 1 to 1603)
  AUTHORS   Yamaguchi,N., Kimura,S., McBride,O.W., Hori,H., Yamada,Y.,
            Kanamori,T., Yamakoshi,H. and Nagai,Y.
  TITLE     Molecular cloning and partial characterization of a novel collagen
```

chain, alpha 1(XVI), consisting of repetitive collagenous domains and cysteine-containing non-collagenous segments
JOURNAL J. Biochem. 112 (6), 856-863 (1992)
PUBMED 1284248
REFERENCE 6 (residues 1 to 1603)
AUTHORS Pan,T.C., Zhang,R.Z., Mattei,M.G., Timpl,R. and Chu,M.L.
TITLE Cloning and chromosomal location of human alpha 1(XVI) collagen
JOURNAL Proc. Natl. Acad. Sci. U.S.A. 89 (14), 6565-6569 (1992)
PUBMED 1631157
COMMENT REVIEWED REFSEQ: This record has been curated by NCBI staff. The reference sequence was derived from M92642.1 and R54778.1.
On Feb 8, 2002 this sequence version replaced gi:11386159.

Summary: This gene encodes the alpha chain of type XVI collagen, a member of the FACIT collagen family (fibril-associated collagens with interrupted helices). Members of this collagen family are found in association with fibril-forming collagens such as type I and II, and serve to maintain the integrity of the extracellular matrix. High levels of type XVI collagen have been found in fibroblasts and keratinocytes, and in smooth muscle and amnion.

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go_function: structural molecule activity [goid 0005198] [evidence IEA];
go_process: cell adhesion [goid 0007155] [evidence IEA];
go_process: pregnancy [goid 0007565] [evidence TAS] [pmid 1284248];
go_process: phosphate transport [goid 0006817] [evidence IEA]"
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1: COL16A1 collagen, type XVI, alpha 1 [*Homo sapiens*]

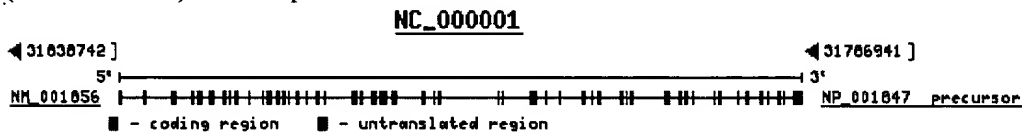
GeneID: 1307 Locus tag: HGNC:2193; MIM: 120326 updated 03-Nov-2005

Summary

Official Symbol: COL16A1 **and Name:** collagen, type XVI, alpha 1 **provided by** HUGO Gene Nomenclature Committee
Gene type: protein coding
Gene name: COL16A1
Gene description: collagen, type XVI, alpha 1
RefSeq status: Reviewed
Organism: *Homo sapiens*
Lineage: *Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Euarchontoglires; Primates; Catarrhini; Hominidae; Homo*
Gene aliases: 447AA; FP1572
Summary: This gene encodes the alpha chain of type XVI collagen, a member of the FACIT collagen family (fibril-associated collagens with interrupted helices). Members of this collagen family are found in association with fibril-forming collagens such as type I and II, and serve to maintain the integrity of the extracellular matrix. High levels of type XVI collagen have been found in fibroblasts and keratinocytes, and in smooth muscle and amnion.

Genomic regions, transcripts, and products

(minus strand) RefSeq below



Genomic context

See COL16A1 in MapViewer

chromosome: 1; **Location:** 1p35-p34

Bibliography

Gene References into Function (GeneRIF): **Submit**

PubMed links

GeneRIFs:

1. interacts with fibrillin-1 and with fibronectin indicating multiple molecular interactions in which this ubiquitously expressed and versatile fibril-associated collagens with interrupted triple helices-collagen can participate — PubMed
2. Not in banded collagen fibrils in dermis, but is component of specialized — PubMed

Entrez Gene Home

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Probe
Protein
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SNP: Genotype
SNP: GeneView
Taxonomy
UniSTS
AceView
Ensembl
Evidence Viewer
GDB
HGNC
HPRD
KEGG
ModelMaker
UCSC
UniGene
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fibrillin-1-containing microfibrils. In cartilage matrix not in aggregates with fibrillin-1. Resides in thin, weakly banded collagen fibrils also containing collagens II and XI.

General gene information

Markers

STS-W96115(e-PCR) (Links: UniSTS: 25967)
Alternate names: RH76723; sts-W96115
SHGC-35321(e-PCR) (Links: UniSTS: 45868)
Alternate names: RH38648; RH50395; SGC35321
G15937(e-PCR) (Links: UniSTS: 72120)
Alternate names: CHLC.UTR_03582_S57132; CHLC.UTR_03582_S57132.P65059
RH69199(e-PCR) (Links: UniSTS: 73013)
Alternate name: M92642
STS-M92642(e-PCR) (Links: UniSTS: 73133)
Alternate names: RH76257; sts-M92642

GeneOntology

Provided by GOA

Function	**Evidence**	
structural molecule activity	IEA	
Process		
cell adhesion	IEA	
phosphate transport	IEA	
pregnancy	TAS	PubMed
Component		
collagen type XVI	TAS	PubMed
cytoplasm	IEA	
extracellular matrix (sensu Metazoa)	IEA	

Homology:
Mouse, Rat
Map Viewer

General protein information

Names: alpha 1 type XVI collagen
alpha 1 type XVI collagen; collagen XVI, alpha-1 polypeptide

NCBI Reference Sequences (RefSeq)

mRNA Sequence NM_001856
Source Sequence M92642,R54778
Product NP_001847 alpha 1 type XVI collagen precursor
Conserved Domains (1) summary
smart00210: TSPN; Thrombospondin N-terminal -like domains
Location: 50 - 231 Blast Score: 419

Related Sequences

Nucleotide		**Protein**
mRNA	AB209571	BAD92808
mRNA	AF370368	AAQ15204
mRNA	M92642	AAA58427
mRNA	R54778	None
mRNA	S57132	AAB25797

mRNA	X14963	CAA33085
mRNA	X15038	CAA33142
	None	Q07092
		Q16593
		Q59F89
		Q71RG9

Additional Links

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